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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 08/921,533 | 09/02/1997 | PERTTI TORMALA | 2880/27 | 9610 |
| 26646 | 7590 | 07/26/2004 | EXAMINER | |
| KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004 | | | CHANNAVAJJALA, LAKSHMI SARADA | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1615 | | |

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 08/921,533 | TORMALA ET AL. |
| | Examiner | Art Unit |
| | Lakshmi S Channavajjala | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 June 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 and 8-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

However, the following rejection has been applied:

- 1. Claims 1-6 and 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4612923 to Kronenthal ('923) in view of US 4,743,257 to Tormala et al ('257)**

'923 teach surgical devices fabricated from a bioabsorbable polymer containing absorbable reinforcing glass filler (claim 1). '923 teach the same polymers and bioabsorbable glasses that are described in the instant specification (col.2). '923 teach glasses having particle size in the range of below 200 or 400 mesh or fibers in the range of 2 to 10 microns (col. 3). Thus, optimizing the particle size so as to enhance the strength of the polymer would have been within the scope of a skilled artisan. '923 teach that the proportion of glass filler in the polymer is not narrowly critical and can vary between 10% and 60%. Further, '923 teach preparing the composite by mixing or blending the polymer with the glass particles. '923 prefer synthetic absorbable polymers as a suitable alternative for metals because of the biodegradable nature of the absorbable polymers. '923 also suggest using the polymer and bioglass matrix for making orthopedic implants or vertebral disc, bone substitutes etc (col.3). '923 fails to teach the reinforcing component ii) of the instant claim. However, instant claims do not state if the reinforcing component ii) and bioglass reinforcing component are same or different. Accordingly, the reinforcing bioglass of '923 reads on the claimed components ii) and iii). Examiner notes that instant claim 2 requires that the second reinforcing fiber is polymer and therefore assumes that component ii) of claim is different from iii).

‘257 teach a self-reinforced surgical osteosynthesis composite material formed about the absorbable polymer or copolymer matrix, which is reinforced with the absorbable reinforcement units and which have the same chemical element percentage composition as the matrix has (col. 3-4). With respect to the method of manufacturing, ‘257 teach mixing together a melt of the absorbable polymer or copolymer and subjecting to heat and pressure (examples and claim 12). ‘257 teach the same polymeric materials such as those claimed in the instant claim 13 for preparing the matrix and the reinforcing element (examples). Figure 1 of ‘257 shows the arrangement of the polymeric matrix and reinforcing fibers in the surgical composite material.

It would have been obvious for one of ordinary skill in the art at the time of the instant invention to self-reinforce absorbable polymer matrix of ‘923 by adding a polymeric reinforcing component because and further mix with the particulate bioglass material because ‘257 teaches that absorbable polymers typically have lower mechanical strength and that reinforcing the matrix with a polymer improves the initial mechanical strength, high tensile, bending or shear strength and toughness of the composite material (col. 2). The expected result is an orthopedic or bone substitute material with increased adhesion upon implanting to the bone and increased strength as well as toughness.

2. Claims 1-6 and 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,743,257 to Tormala et al (‘257) in view of Doyle et al (Biomaterials 1991).

‘257, discussed above, teach a bioabsorbable composite material comprising a polymeric matrix that is reinforced with the absorbable reinforcement units having same chemical composition as that of the matrix, for manufacturing osteosynthesis devices such as nails, pins

etc. Instant claims do not state if the polymer matrix and the reinforcing component ii) are same or different. Accordingly, the self-reinforcing polymer of '257 meets the claimed components i) and ii). '257 fail to teach mixing a bioceramic or bioactive glass with the absorbable polymer of the composite material and the volume fractions claimed in the instant application. '257 fail to teach the claimed bioglass reinforcing material.

Doyle et al teaches polyhydroxybutyrate (PHB) polymer reinforced with hydroxyapatite for favorable bone tissue adaptation and for imparting stiffness to the composite. Doyle et al teaches that the composite has advantages over the non-biodegradable composite in bone applications (page 842). PHB further suggests hydroxyapatite powder in the form of particles having a size of 8.6 microns (page 842). Doyle teaches the use of composite in bone fractures and bone fixation. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the particulate bioglass having the claimed micron sizes in the composite of '257 comprising resorbable polymer that is self reinforcing because Doyle teaches that the composite comprising bioabsorbable polymer together with the bioglass of 0.2. The expected result is a composite material with increased adhesion upon implanting to the bone and increased strength as well as toughness.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-6 and 8-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,406,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and patented claims are drawn to a bioabsorbable polymer comprising a polymer matrix, bioglass particles and a reinforcing element. Instant claims do not state if the component ii) (reinforcing element) is the same as polymer or is it similar to the bioglass composite. Assuming that component ii) is the same as polymer, and then the polymer matrix and self-reinforced matrix of the patent claims is same as that of claimed components 1 and 2. Further, patented claims state that the pores are filled by the reinforcement polymer fibers and also recites the bioglass as particles. The difference between patent and instant claims lies in the particle size and the volume fraction. However optimizing the amount of bioglass and the particle size so as to achieve the composite having the desired effect upon administering at the site i.e., as stiffness or elasticity etc would have been within the scope of a skilled artisan.

Response to Arguments

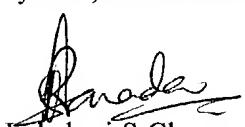
Applicant's arguments with respect to claims 1-6 and 8-22 have been considered but are moot in view of the new ground(s) of rejection.

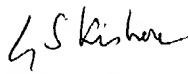
Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615
July 23, 2004


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500